

REMARKS/ARGUMENTS

By this Amendment, claim 10 is canceled, claim 8 is amended. Claims 4 - 5, and 8 are pending.

Citations to the Specification are directed to U.S. Patent Application Publication No. 2005/0234071 (Parthasaradhi et al.).

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

Applicants hereby affirm their prior election without traverse of Group II, claims 4 – 5, 8 and 10, reserving their rights under 35 USC § 121 to file a divisional application for the nonelected claims.

Rejection under 35 USC § 112 second paragraph

Claims 8 and 10 stand rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed.

With regard to claim 8, the Examiner sets forth that a process claim, should not depend on claim 4 (a compound claim) for any definition since the two claims (compound and process) are independent and distinct. Without acquiescing to the propriety of the Examiner's rejection, and solely to expedite prosecution, claim 8 has been amended to remove the reference to claim 4.

With regard to claim 10 the Examiner argues that the claim is indefinite because the claim is dependent on cancelled claim 3. Without acquiescing to the propriety of the Examiner's rejection, and solely to expedite prosecution, claim 10 has been canceled herein.

Accordingly, reconsideration and withdrawal of the rejection under 35 USC 112 second

paragraph is respectfully requested.

Rejection under 35 USC § 102(b)

Claims 4 - 5, 8 and 10 stand rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Oshiro et al., (U.S. Patent 5,006,528). This rejection is respectfully traversed.

In Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (MPEP 2131), the CAFC set forth that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference". In the instant case, not every element of the claims is present in the '528 (Oshiro et al.) patent.

With regard to claim 10, without acquiescing to the propriety of the Examiner's rejection, and solely to expedite prosecution, claim 10 has been canceled herein.

The Examiner argues that the '528 (Oshiro et al.) patent discloses an aripiprazole compound and process of preparing the compound, citing column 11, lines 8-9 for the compound and column 11 bridging column 12, lines 1-23 for the process for preparing the compound. The Examiner alleges that the reference discloses that alcohols such as methanol can be use to isolate the salt (citing column 5, line 1-5). The Examiner further alleges that Applicant must show that their crystalline form is different from any of the ones prepared in the prior art (Office Action at page 4).

However, if the Examiner is arguing that the '528 (Oshiro et al.) patent inherently discloses the aripiprazole methanolate as instantly claimed, then the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed.

Cir. 1993). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). Here, the Examiner has not met that burden by alleging that Applicant needs to show the aripiprazole methanolate form is different from any of the ones prepared in the prior art. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

Here, the allegedly inherent characteristic does not necessarily flows from the teachings of the applied prior art, because the claims are directed to aripiprazole methanolate, which is not disclosed in the '528 (Oshiro et al.) patent. This solvate form of aripiprazole is not disclosed in the '528 (Oshiro et al.) patent, and the methods as disclosed in the '528 (Oshiro et al.) patent will not yield a solvate form of aripiprazole. In addition, the claims are directed to aripiprazole methanolate wherein the methanol content is between about 2 to 6% of the weight of aripiprazole methanolate, which is not disclosed in the '528 (Oshiro et al.) patent. Furthermore, the '528 (Oshiro et al.) patent does not does not disclose a process for the preparation of aripiprazole methanolate by preparing a solution of aripiprazole in a mixture of methanol and tetrahydrofuran, then isolating the aripiprazole methanolate.

Accordingly, reconsideration and withdrawal of the rejection of pending claims 4 - 5, and

Application No. 10/518,214
Amendment Dated 6/25/2008
Reply to Office Action of 12/27/2008

8 under 35 USC 102(b) is respectfully requested.

* * *

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

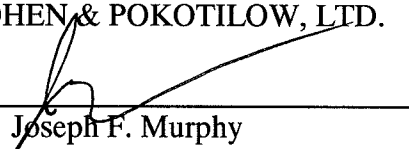
Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW, LTD.

June 25, 2008

Please charge or credit our
Account No. 03-0075 as necessary
to effect entry and/or ensure
consideration of this submission.

By 
Joseph F. Murphy
Registration No. 58,313
Customer No. 03000
(215) 567-2010
Attorneys for Applicants